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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,333	02/21/2001	Lanfranco Callegaro	204,940	9321

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EXAMINER

DI NOLA BARON, LILIANA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 10/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,333

Applicant(s)

CALLEGARO ET AL.

Examiner

Liliana Di Nola-Baron

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Applicant's amendment, filed on August 2, 2002, is acknowledged.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 25-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al. alone, or in view of Cialdi et al. or Khan et al. or Nicholas et al.

The claimed invention refers to a matrix comprising at least one hyaluronic acid (HA) or derivative thereof, and a biological material comprising said matrix and intestinal cells.

Burns et al. provides a method for promoting cell growth and proliferation, comprising admixing cells with a water-insoluble biocompatible matrix containing a derivative of a polyanionic polysaccharide (PAS), and teaches that in a preferred embodiment the cells are fibroblasts and the matrix is placed at the site of the skin lesion, such as wound burn or dermal ulcer (See e.g., col. 4, line 22 to col. 5, line 16). Burns et al. teaches that derivatives of PAS include the addition of functional groups, such as substituted amide groups, ester linkages and amine groups, and reactions that increase the water insolubility by crosslinking the PAS molecules or non-covalent interactions (See e.g., col. 5, lines 29-45). Burns et al. includes HA among the PAS used in the invention and teaches that fibers and other shaped articles can be formed using techniques well known in the art, including wet spinning and weaving (See e.g.,

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col. 7, line 36 to col. 8, line 29). In Example 5, Burns et al. teaches that the purpose of the matrix is to give support to the cells for implantation and the PAS composites can be used as matrix.

Thus, Burns et al. discloses a matrix comprising derivatives of HA and cells, used as support for cell proliferation and placed at the site of skin lesions, including ulcers. Burns et al. does not specify all the HA derivatives contemplated in the instant application.

Cialdi et al. provides HA derivatives, including esters of HA with alcohols of the aliphatic, araliphatic, heterocyclic and cycloaliphatic series, and sulfated derivatives, which are used as anti-inflammatory agents in different forms, including non-woven fabrics (See e.g., cols.2-3).

Khan et al. discloses HA ester derivatives, including succinic hemiesters for the treatment of burns and other disorders (See e.g., Abstract).

Nicolais et al. provides HA esters and crosslinked esters for bone replacement (See e.g., Abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Burns et al. alone or in view of Cialdi et al., Khan et al. or Nicolais et al., to device a matrix comprising at least one hyaluronic acid or derivative thereof, and a biological material comprising said matrix and intestinal cells.

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Because of the teachings of Burns et al., that derivatives of HA can be used in the invention, one of ordinary skill in the art would have a reasonable expectation that the compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

3. Claims 25-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al.

Valentini et al. provides derivatives of HA as raw material to fabricate porous, degradable scaffolds for tissue repair and wound healing (See e.g., col. 1, lines 64-67). Valentini et al. teaches that the scaffolds can have any size and shape and can be used for attachment of bioactive molecules (See e.g., col. 2, lines 7-22). Valentini et al. teaches that the scaffold is a three-dimensional structure of interconnected pores, which permit cell ingrowth and most preferably the HA derivative is HA esterified with a benzyl moiety (See e.g., col. 2, lines 54-67). Additionally, Valentini et al. teaches that the scaffolds may be used for the treatment of ulcers and to promote tissue culture (See e.g., col. 7, line 52 to col. 8, line 17).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Valentini et al. to device a matrix comprising at least one hyaluronic acid or derivative thereof, and a biological material comprising said matrix and intestinal cells.

Because of the teachings of Valentini et al., that derivatives of HA can be used in the invention, one of ordinary skill in the art would have a reasonable expectation that the compositions

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claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

4. Applicant's arguments filed on August 2, 2002 have been fully considered but they are not persuasive.

5. Applicant argues that the prior art (Burns et al.) contains a hydrophobic polymer as an essential component, whereas the claimed matrix only comprises HA or derivatives thereof. In response to said argument, it is noted that the "comprising" language of the instant claims allows for additional components in the matrix. Furthermore, the burden is shifted to Applicant to show that additional ingredients disclosed by the prior art would be detrimental to the process and compositions claimed in the instant application.

6. In response to Applicant's argument, that Burns et al. highlights the improved properties of the compositions comprising polysaccharide and polymer, when compared to the composition comprising only polysaccharide, it is noted that in the Examples provided Burns et al. compares HA/CMC films or foams coated with PGA or PLA polymer, versus uncoated HA/CMC films or foams. Thus, the prior art does not teach against using compositions comprising only the polysaccharide.

7. In reply to Applicant's argument, that Valentini et al. discloses three-dimensional structure of interconnected pores, it is noted that the nonwoven fabric or perforated membrane matrix claimed in the instant application can be porous. Furthermore, nowhere Valentini et al.

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indicates that the structures of the invention are sponges, and the process claimed in the instant application does not read on method steps showing differences over the prior art.

8. In response to Applicant's argument, that Valentini et al. discloses the use of the invention in the treatment of ulcers among a plethora of different and only potential uses, it is noted that Valentini et al. teaches that the scaffolds may be used for the treatment of ulcers and to promote tissue culture (See e.g., col. 7, line 52 to col. 8, line 17). If the prior art structure is capable of performing the intended use, then it meets the limitations of the claims.

Conclusion

Claims 25-44 are rejected.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

Senes

October 3, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600